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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/528,103
Filing Date: October 03, 2005
Appellant: SCHLUETER, HARTMUT

Harry B. Shubin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 5, 2009 appealing from the Office action mailed August 5, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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U.S. Patent Publication No. CRAMER et al. 11-2001

2001/0047086

U.S. Patent No. 6,342,160 WELCH et al. 1-2002

U.S. Patent Publication No. MacPHEE et al. 08-2003

2003/0161753

U.S. Patent Publication No. SNYDER et al. 08-2005

2005/0182242

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Appellant is relying on the instant specification's use of the term "eluate" to support the phrases "elution chromatography" and "whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained". Appellant is also relying upon paragraph 5 of the primary reference, Cramer (U.S. Patent Publication No. 2001/0047086), for a distinction between elution chromatography and displacement chromatography. It is clear from the first sentence of paragraph 6 of Cramer (U.S. Patent Publication No. 2001/0047086) that displacement chromatography uses an eluant. Displacement chromatography differs from elution chromatography in that the eluant contains a displacer. Thus, the

fact that appellant's specification uses the term "eluates" is equally supportive of both elution and displacement chromatography. As such, there is no support in the specification for precluding displacement chromatography. The phrases "elution chromatography" and "whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained" are drawn to new matter because they are being used to preclude displacement chromatography and the instant specification does not have any support for precluding displacement chromatography. Accordingly, the claims are considered to be drawn to new matter.

Claims 1-7 and 10 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cramer (U.S. Patent Publication No. 2001/0047086). The claims are considered to read on Cramer (U.S. Patent Publication No. 2001/0047086). The preamble of claim 1 is directed to "discovering chromatography parameters." Many of the parameters that Cramer (U.S. Patent Publication No. 2001/0047086) uses are equally applicable to both "elution chromatography" and "displacement chromatography." These parameters would include the last line of Cramer (U.S. Patent Publication No. 2001/0047086)'s Abstract such as "different stationary phase materials, biomolecules, and modes of interaction." This would include Cramer (U.S. Patent Publication No. 2001/0047086)'s penultimate sentence of paragraph 9 of "the identification of important properties for a particular interaction or for similar interactions on different stationary phases." This would include Cramer (U.S. Patent Publication No. 2001/0047086)'s paragraphs 18 and 33 "determining the equilibrium concentration of the bioproduct." As such, Cramer (U.S.

Patent Publication No. 2001/0047086) discloses “discovering suitable elution chromatograph parameters.” The preamble of claim 1 is also directed to an automated method. This is disclosed in Cramer (U.S. Patent Publication No. 2001/0047086) on paragraph 53, particularly lines 4-6. Claim 1, step a is disclosed in the last four lines of paragraph 30 of Cramer (U.S. Patent Publication No. 2001/0047086) and in Figure 1. Claim 1, step b is disclosed in paragraphs 17 and 33 of Cramer (U.S. Patent Publication No. 2001/0047086). Claim 1, step c’s different chromatographic parameters is disclosed in the last sentence of the Abstract and the penultimate sentence of paragraph 9 of Cramer (U.S. Patent Publication No. 2001/0047086). Claim 1, steps d and e’s separation and analysis is disclosed in paragraph 18 of Cramer (U.S. Patent Publication No. 2001/0047086). The ascertaining of parameters is disclosed in Cramer (U.S. Patent Publication No. 2001/0047086) in the last three lines of the Abstract, the penultimate sentence of paragraph 9, paragraphs 16-18, and paragraph 33. However, if a difference exists between the claims and Cramer (U.S. Patent Publication No. 2001/0047086), it would reside in optimizing the steps of Cramer (U.S. Patent Publication No. 2001/0047086). It would have been obvious to optimize the steps of Cramer (U.S. Patent Publication No. 2001/0047086) to enhance separation.

Claims 1-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160). At best, the claims differ from Cramer (U.S. Patent Publication No. 2001/0047086) in reciting elution chromatography. Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and

column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem. It would have been obvious that Cramer (U.S. Patent Publication No. 2001/0047086)'s method would reveal suitable elution chromatography parameters because Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Cramer (U.S. Patent Publication No. 2001/0047086) alone or Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) as applied to claims 1-7 and 10 above, and further in view of each of MacPhee (U.S. Patent No. 2003/0161753), Snyder (U.S. Patent Publication No. 2005/0182242), and Pantoliano (U.S. Patent No. 6,214,293). At best, the claim differs from either Cramer (U.S. Patent Publication No. 2001/0047086) alone or Cramer (U.S. Patent Publication No. 2001/0047086) in reciting use of a stabilizer. MacPhee (U.S. Patent No. 2003/0161753) (paragraph 38, lines 3, 19, 20, and 32) discloses stabilizing biological materials with glycerol reduces damage to the biological material. Snyder (U.S. Patent Publication No. 2005/0182242) (paragraphs 120 and 121) discloses that glycerol stabilizes protein. Pantoliano (U.S. Patent No. 6,214,293) (column 6, lines 11-24 and column 57, lines 25-31) discloses glycerol stabilizes protein. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) alone or Cramer (U.S.

Patent Publication No. 2001/0047086) because MacPhee (U.S. Patent No. 2003/0161753) (paragraph 38, lines 3, 19, 20, and 32) discloses stabilizing biological materials with glycerol reduces damage to the biological material. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) because Snyder (U.S. Patent Publication No. 2005/0182242) (paragraphs 120 and 121) discloses that glycerol stabilizes protein. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) because Pantoliano (U.S. Patent No. 6,214,293) (column 6, lines 11-24 and column 57, lines 25-31) discloses glycerol stabilizes protein.

(10) Response to Argument

Appellant urges phrases “elution chromatography” and “whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained” are supported because the term “eluates” is used in the specification. However, appellant is relying upon paragraph 5 of the primary reference, Cramer (U.S. Patent Publication No. 2001/0047086), for a distinction between elution chromatography and displacement chromatography. It is clear from the first sentence of paragraph 6 of Cramer (U.S. Patent Publication No. 2001/0047086) that displacement chromatography uses an eluant. Displacement chromatography differs from elution chromatography in that the eluant contains a displacer. Thus, the fact that appellant’s specification uses the term “eluates” is equally supportive of both elution and displacement chromatography. As such, there is no support in the specification for precluding

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displacement chromatography. The phrases “elution chromatography” and “whereby suitable elution chromatography parameters for separating the biological into biomolecules are ascertained” are drawn to new matter because they are being used to preclude displacement chromatography and the instant specification does not have any support for precluding displacement chromatography.

Appellant urges patentability over Cramer (U.S. Patent Publication No. 2001/0047086) based upon the new matter limitation “elution chromatography” as opposed to “displacement chromatography”. However, chromatography is not performed in the claimed method. The claims are actually directed to “discovering parameters.” Many of the parameters that Cramer (U.S. Patent Publication No. 2001/0047086) uses are equally applicable to both “elution chromatography” and “displacement chromatography.” These parameters would include the last line of Cramer (U.S. Patent Publication No. 2001/0047086)’s Abstract such as “different stationary phase materials, biomolecules, and modes of interaction.” This would include Cramer (U.S. Patent Publication No. 2001/0047086)’s penultimate sentence of paragraph 9 of “the identification of important properties for a particular interaction or for similar interactions on different stationary phases.” This would include Cramer (U.S. Patent Publication No. 2001/0047086)’s paragraphs 18 and 33 “determining the equilibrium concentration of the bioproduct.” As such, Cramer (U.S. Patent Publication No. 2001/0047086) discloses “discovering suitable elution chromatograph parameters.”

Appellant urges patentability over Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) based upon the allegation

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that Welch (U.S. Patent No. 6,342,160) is not directed to elution chromatography.

However, the mobile phase disclosed on the bottom of Figure 15 of Welch (U.S. Patent No. 6,342,160) is hexane/isopropyl alcohol/acetic acid. As such, it is directed to a conventional eluant without a displacer. Accordingly, Welch (U.S. Patent No. 6,342,160) is considered to be directed to elution chromatography. In any event, Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem. This is precisely the “discovering parameters” that the appealed claims are directed to. “Gel media”, i.e., adsorbent, is specifically listed on page 4, lines 17-20 of appellant’s specification.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ernest G. Therkorn/
Ernest G. Therkorn
Primary Examiner
Art Unit 1797

EGT
4/16/09

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